

How To: Apply Ethics to Clinical Audit

INTRODUCTION

The aim of this 'How To' guide is to provide advice on how to apply ethics to clinical audit. Unlike research, clinical audit projects do not need to be submitted to a Research Ethics Committee (REC) for ethical approval. This is one of the key reasons why you must ensure that your project is clinical audit rather than research. If you think that there are ethical issues with your project you must discuss these with your divisional Clinical Audit Facilitator at the planning stage. Aspects of this guide are discussed in more detail in:

- What is Clinical Audit.
- How To: Set an Audit Sample and Design your Data Collection & Data Collection Form.
- How To: Engage Patients, Service Users & Carers in Clinical Audit.

ETHICS AND CLINICAL AUDIT

The starting point in any consideration of ethics is to remember that your audit project should benefit patients and not do harm.

Clinical audit must always be conducted within an ethical framework. At a practical level, this means ensuring patient and staff confidentiality and ensuring that data is collected and stored appropriately. As someone involved in clinical audit, you should be aware of the following pieces of legislation and national guidance:

CALDICOTT PRINCIPLES (1997)

The Caldicott Committee was established by the Chief Medical Officer to review all patient identifiable information which passes from NHS organisations to other NHS or non NHS bodies for purposes other than direct care, medical research, or where there is a statutory requirement for information.

The Committee considered that, whilst no single data item could be relied upon to identify an individual with certainty, there were many items being transferred between organisations which, when taken together, could permit identity to be inferred. They concluded that **all** items of information which related to an attribute of an individual should be treated as potentially capable of identifying patients to a greater or lesser extent, and should be appropriately protected to safeguard confidentiality.

The principles and recommendations made by the Committee emphasised the need for controls over the availability of patient identifiable information and access to it. In particular a Caldicott Guardian, appointed in each NHS organisation, with specific responsibilities to oversee an ongoing process of audit, improvement and control.

The six Caldicott principles that applied to the handling of patient identifiable information are:

- Justify the purpose(s) of using confidential information.
- Only use it when absolutely necessary.
- Use the minimum that is required.
- Access should be on a strict need-to-know basis.
- Everyone must understand his or her responsibilities.
- Understand and comply with the law.

DATA PROTECTION ACT (1998)

This Act regulates the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. It relates to personal data, that is, data which relates to a living individual who can be identified from that data, or when combined with other information possessed.

Anyone processing personal information must comply with eight enforceable principles of good information handling practice. These say that data must be:

1. Fairly and lawfully processed.
2. Processed for limited purposes.
3. Adequate, relevant and not excessive.
4. Accurate and up to date.
5. Not kept for longer than is necessary.
6. Processed in line with your rights.
7. Secure.
8. Not transferred to countries without adequate protection.

Health information, e.g. data about a person's physical or mental health or condition, is classified as 'sensitive personal data'. The Act allows for this to be lawfully processed where necessary for medical purposes, when undertaken by a health professional, or a person who owes an equivalent duty of confidentiality. This includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

NHS CONFIDENTIALITY CODE OF PRACTICE (2003)

This contains practical guidance for NHS staff and others on how to treat patient information with respect in the context of a modern health service. It is endorsed by the Information Commissioner, the General Medical Council and the British Medical Association and is entirely consistent with Data Protection requirements.

It aims to ensure that all patient information is processed fairly, lawfully and as transparently as possible so that the public:

- Understand the reasons for processing personal information.
- Give their consent for the disclosure and use of their personal information.
- Gain trust in the way the NHS handles information.
- Understand their rights to access information held about them.

It states that there are situations where consent cannot be obtained for the use or disclosure of patient identifiable information, yet the public good of this use outweighs issues of privacy. Section 60 of the Health and Social Care Act 2001 currently provides an interim power to ensure that patient identifiable information, needed to support a range of important work such as clinical audit, record validation and research, can be used without the consent of patients. It also states that where reasonable efforts are made to ensure that patients understand how their information is to be used to support their healthcare, consent can be implied, providing that "need to know" principles are enforced.

WHAT ARE THE IMPLICATIONS FOR CLINICAL AUDIT?

Essentially, the documents outlined above allow for the use of patient data for the purposes of clinical audit, that is, to review and improve healthcare. All Trust staff are automatically bound by the necessary duty of confidentiality. However, data should not be reviewed by non Trust staff unless a similar duty of confidentiality is in place, for example in the case of medical students.

Note that UHBristol publishes a Patient Information leaflet, "*What we do with your personal information*", which mentions that data about a patient's treatment and care may be used for purposes including clinical audit. There are also some suggested points of contact if patients have any concerns about this.

- Data Collection - In order to comply with the Data Protection Act and to ensure patient anonymity, personal details, including hospital ID number, name, address, date of birth etc, should not be recorded

on the data collection form. Therefore the best approach is to number each of your forms using a unique identifier. A separate piece of paper, or 'code sheet' should then be kept as a key, which links each unique identifier to the patients hospital number. Without this list, data collection forms cannot be linked to specific patients. The key would need to be destroyed when the audit analysis is complete. This also applies to data held on databases. Occasionally it might be necessary to record patient identifiable information on the data collection form. For example during a prospective data collection exercise the data collection form might have to follow a patient through their pathway of care. In this instance the only patient identifiable information that should be recorded on the form is their hospital ID number. Name, date of birth, etc should never be recorded.

- Adequate, relevant and not excessive. Ensure data is being collected for the stated purpose of clinical audit rather than research or other service improvement activities and collect only the data you need to answer your audit objectives and standards, bearing in mind the 'adequate, relevant and not excessive' Data Protection Act principle.
- Data should be kept securely - This relates to both electronic and hard copies of data. Any patient identifiable clinical audit data must be kept securely. Audit proformas should be locked in a filing cabinet, electronic files should be password protected or kept on a secure, restricted access server and ensuring that only clinical professionals with a duty of confidentiality are able to access the data. Person identifiable information should not be stored on personal laptop computers or e-mailed to non NHS e-mail accounts. Data can only be e-mailed to UHBristol e-mail addresses or NHS.net. Situations should be avoided that might allow public access to personal data, such as leaving patient files in the boot of your car. Your car could be stolen with the files in it.
- Data should not be kept for any longer than necessary - Remember to destroy completed audit proformas once an audit has been completed. Double-check with other members of the audit team first though and make sure you have kept enough summarised data to allow comparison with any re-audit data you may collect in future.

CLINICAL STAFF CONFIDENTIALITY

It is also important to remember that clinical audit reports and presentations should not identify clinicians by name unless the people concerned have agreed to this.

DO YOU NEED ETHICS APPROVAL FOR AUDIT?

Whilst research needs to be submitted to REC for ethical approval, clinical audit does not. However, whilst clinical audit by definition does not involve anything being done to patients beyond their routine clinical management and therefore does not require formal ethical approval, it should still be conducted within an ethical framework. By approving and registering a project as a clinical audit, the Trust is stating that the project fulfils the methodological criteria that allows for patient data to be accessed and analysed.

However, before assuming that you do not require ethical approval, it is important to consider:

1. IS YOUR PROJECT REALLY A CLINICAL AUDIT PROJECT?

Decisions about whether projects need ethical approval often hinge on the question of whether they really are clinical audit, or whether they are actually research. Remember that clinical audit asks the questions "are we following best practice?" and "what is happening to patients as a result?"

Clinical audit projects never involve:

- A completely new treatment or practice.
- The use of control groups or placebo treatments.
- Any disturbance to the patient beyond that required for routine clinical management.
- Allocating patients randomly to different treatment groups.

Clinical audit may, however, involve input from patients at a number of levels, e.g.

- Patients may be asked to participate in surveys which help to determine whether standards have been met.
- Patients may be involved in the design of individual audit projects or indeed whole programmes of activity, e.g. as members of steering groups.

Sometimes healthcare professionals undertake what they mistakenly think is 'clinical audit', when what they are really doing is research. Research always requires ethical approval. Calling research by any other name does not remove this requirement.

If you are unsure whether or not the project that you want to undertake is clinical audit or research your divisional Clinical Audit Facilitator will be able to advise. Very occasionally liaison might be required between your divisional Clinical Audit Facilitator, the Research & Effectiveness Department and the local REC. If the conclusion is that you are undertaking research, you must formally submit the appropriate paperwork to the local REC for ethics approval.

If on the other hand your project contains an element of both clinical audit and research, you will need to obtain formal ethical approval for the research component of the project from REC and submit a completed copy of the clinical audit proposal form to your divisional Clinical Audit Facilitator for the clinical audit component.

2. DOES YOUR PROJECT INCLUDE A PATIENT SURVEY?

Patient surveys can be construed as doing something to patients 'beyond normal clinical management'. It is therefore important to take advice on the design of patient surveys. Planned questions could touch upon potentially sensitive matters, giving rise to ethical concerns. Any patient surveys should be designed in such a manner as to cause minimum possible disruption to patients.

All structured surveys, staff or patient, administered by post, in hospital, or via a one-to-one interview, undertaken for clinical audit are subject to approval by the Questionnaire, Interview and Survey (QIS) Group. The contact details for the QIS group are listed at the end of this guide. The QIS group offers advice on survey design and is responsible for monitoring all survey activity at the Trust. Please contact Paul Lewis, the Patient Involvement Facilitator for advice on structured surveys/ questionnaires. If you require advice on unstructured interviews and focus groups, this should be discussed with Tony Watkin, the Trust's Public Involvement Project Lead. The contact details for Paul Lewis and Tony Watkin are listed at the end of this guide.

Formal Research projects are subject to ethical approval by the local REC and therefore do not require QIS approval.

When undertaking a survey it is important to consider the patient's, service users or carers rights, dignity and time. Should you wish to undertake a survey as part of your clinical audit project there are a number of ethical questions that you should consider. These are:

- Is the information that you are seeking already available? The QIS group may not approve projects if it feels that one group of patients is being excessively targeted.
- Is it necessary to carry out a survey? Surveys should only ask for information that cannot be collected from another source and that is related to processes or the outcome of care, i.e. were standards of best practice being met.
- Will it add value to the clinical audit project? Carrying out a survey unnecessarily, or asking more questions than necessary, will not add value to your project. Keep your questionnaire succinct. It is important not to bombard patients with too many questions as they might choose not to participate if the questionnaire looks too long; up to 20 questions is usually sufficient.
- Have you checked your sample? Your sample, if postal survey, should be checked against the latest hospital records, as sending questionnaires to deceased patients is a frequent error that can cause

distress to relatives. Similarly, getting patients' names or other details slightly wrong can also cause offence.

- What written information will be given to the subject to explain what the survey is about? Include a covering letter with all patient questionnaires. A template covering letter is available on the QIS intranet site. The intranet details are listed at the end of this guide. The letter should include contact details should the patient have any queries that they wish to be answered quickly about the questionnaire, the background to project and reason for contacting the patients, instructions on how to return the completed questionnaire, a statement on how you will protect the patient's confidentiality, ideally this should be achieved through developing completely anonymised questionnaires, and what you intend to do with the data collected.
- How will you ensure that patients freely consent to taking part? Patients must not be coerced into taking part and must have the option to decline or withdraw without detriment or antagonism.
- Is your survey addressing a sensitive topic? Where patients are being asked questions about their clinical care, it is important that questions are not phrased inappropriately/insensitively, as this might inadvertently cause harm.
- Will the survey interfere with the treatment of the patient? Your survey should not cause the patient to reflect negatively upon their course of treatment, thereby jeopardising clinical outcomes.

If you are in any doubt about whether your survey raises ethical concerns please discuss with your divisional Clinical Audit Facilitator.

3. ARE YOU PLANNING TO PUBLISH?

Clinical Audits are usually published because the topic and/or methodology may be of interest to a wider audience, for instance, demonstrating how an audit cycle was successfully followed after initially poor results against standards, by implementing changes and demonstrating an improvement in practice with a re-audit.

Whilst clinical audit projects may be published without ethical approval, e.g. the Quality Improvement Reports published by the British Medical Journal, journal editors may refuse to publish articles if there are ethical concerns and REC ethical approval has not been granted. If you want to publish because of the results of your project, rather than to share the methodology, you should question whether you are undertaking a research activity, rather than a clinical audit project, that should have been submitted to REC for ethical approval. If you intend to publish your clinical audit project this should be discussed with your Clinical Audit Facilitator at the beginning of your project.

REFERENCES

- Data Protection Act (1998) available [on-line]
www.informationcommissioner.gov.uk/eventual.aspx?id=34
- Caldicott Committee Report (1997) available [on-line]
www.dh.gov.uk/assetRoot/04/06/84/04/04068404.pdf
NHS Confidentiality Code of practice (2003) available [on-line]
www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf
Note that figure 5 (p19) contains practical advice on keeping information secure, and figure 6 (p20) nicely summarises the relevant Caldicott principles.
- Health & Social Care Act (2001), Section 60 available [on-line]
www.legislation.hms.gov.uk/acts/acts2001/10015--g.htm
- "What we do with your personal information", UHBristol Patient Information leaflet, February 2008 available [intranet]
<http://www.avon.nhs.uk/dms/download.aspx?did=1655>

CONTACT DETAILS/ USEFUL INFORMATION

CLINICAL AUDIT

- The UHBristol **Clinical Audit website** is available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit.html>
- Contact details for the UHBristol **Clinical Audit Team** are available from the Clinical Audit Central Office or [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/contacts.html>
- The full range of UHBristol **'How To' guides** are available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/how-to-guides.html>
- A copy of the UHBristol **Proposal Form, Presentation Template, Report Template, Summary Form, and Action Form** are available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/doing-projects-at-ubht.html>
- The UHBristol **Clinical Audit Central Office** can be contacted on tel. (0117) 342 3614 or e-mail: stuart.metcalfe@uhbristol.nhs.uk
- **Clinical Audit Training Workshops** can be booked through the Clinical Audit Central Office.

CLINICAL EFFECTIVENESS

- For advice on **Clinical Effectiveness**, including how to write guidelines, contact James Osborne, Clinical Effectiveness Co-ordinator, tel. (0117) 928 3827 or e-mail: james.osbourne@uhbristol.nhs.uk

PATIENT ENGAGEMENT

- For advice on **Patient Involvement**, including **designing structured surveys and questionnaires** contact Paul Lewis, Patient Involvement Facilitator, tel. (0117) 928 3638 or e-mail: paul.lewis@UHBristol.nhs.uk
- For advice on **Patient Involvement**, including **unstructured surveys and focus groups** contact Tony Watkin, Public Involvement Lead, tel. (0117) 928 3729 or e-mail: tony.watkin@UHBristol.nhs.uk
- Surveys MUST be approved by the Trust's **Questionnaire, Interview and Survey (QIS) Group**. Proposals should be submitted to Paul Lewis using the QIS proposal form. The proposal form is available [online] via <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/doing-projects-at-ubht.html>
- A copy of the UHBristol **Covering Letter** template is available [online] via the internal intranet site <http://connect/Governance/patientexperience/ppi/Pages/QISGroup.aspx>

RESEARCH

- For advice on research projects contact the **Research & Development Department**, tel. (0117) 342 0233 or e-mail: r&doffice@uhbristol.nhs.uk

LITERATURE REVIEWS

- For advice on literature reviews contact the **Learning Resource Centre**, tel. 0117 342 0105 or e-mail: learningresources@UHBristol.nhs.uk

SAMPLE SIZES

- The **Sample Size Calculator** is available [online] via: <http://www.uhbristol.nhs.uk/healthcare-professionals/clinical-audit/how-to-guides.html>